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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/700,851	11/03/2003	Yoh-ichi Matsumoto	019026 000110US	3540

7590 04/17/2007
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EXAMINER

SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/17/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

09/700,851

Applicant(s)

MATSUMOTO ET AL.

Examiner

Rodney P. Swartz, Ph.D.

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22November2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 5-23,25 and 29-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 5-23,25 and 29-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1645

DETAILED ACTION

1. Applicants' Response to Office Action, received 22 November 2006, is acknowledged. Claims 1-4, 24, and 26-28 are canceled. Claims 5, 6, 7, 8, 11, 12, 13, 14, 15, 16, 17, 18, 20, 22, 23, 25, 29, 32, and 33 are amended.
2. Claims 5-23, 25, and 29-33 are pending and under consideration.

Deposit Requirement

3. Applicants argue that a deposit is not necessary in view of the provision of amino acid sequences and corresponding cDNA sequences and by reference to these sequences rather than its laboratory name in the amended claims.

The examiner has considered applicants' argument, but does not find it persuasive. While the partial sequences may be made known, the actual binding characteristics of an antibody is due to its configuration of the binding moiety, not just sequence data.

The requirement for deposit of the antibody VTm1.1 is maintained.

Rejections Objections Moot/Withdrawn

4. The rejection of claims 1-4, 24, and 26-28 under 35 U.S.C. 112, first paragraph, scope of enablement for humanized mouse antibodies which bind specifically to VT2 and/or VT2 variant, is moot in light of the cancelation of the claims.
5. The objection to claims 7, 11-17, 20, and 33 is withdrawn in light of the claim amendments.
6. The rejection of claim 6 under 35 U.S.C. 101, is withdrawn in light of the claim amendment.

Art Unit: 1645

7. The rejection of claims 5, 6, 12, 18-19, 21, 23, 28, and 29 under 35 U.S.C. 112, second paragraph, indefiniteness for laboratory designation, is withdrawn in light of the amendments of the claims.
8. The rejection of claim 28 under 35 U.S.C. 112, second paragraph, indefiniteness for laboratory designation, is moot in light of the cancellation of the claim.
9. The rejection of claims 5-10, 12-13, 18-19, 21, 23, 28, and 29 under 35 U.S.C. 112, second paragraph, indefiniteness for identity of antibody, is withdrawn in light of the amendments of the claims.
10. The rejection of claim 28 under 35 U.S.C. 112, second paragraph, indefiniteness for identity of antibody, is moot in light of the cancellation of the claim.
11. The rejection of claims 5-13, 18-19, 21, 23, 28, and 29 under 35 U.S.C. 112, second paragraph, indefiniteness for sequences "as shown in Fig. X", is withdrawn in light of the amendment of the claims.
12. The rejection of claim 28 under 35 U.S.C. 112, second paragraph, indefiniteness for sequences "as shown in Fig. X", is moot in light of the cancellation of the claim.

Rejections Maintained

13. The rejection of claims 7-10 and 13 under 35 U.S.C. 112, second paragraph, indefiniteness for laboratory designation, is maintained for reasons of record.

Applicants argue that the amendments of the claims obviates the rejection.

The examiner has considered applicants' argument, but does not find it persuasive because the claims retain the designation of VTm1.1 antibody.

Art Unit: 1645

14. The rejection of claims 6-23, 25, and 29-33 under 35 U.S.C. 112, first paragraph, scope of enablement for humanized mouse antibodies which bind specifically to VT2 and/or VT2 variant, is maintained for reasons of record.

Applicants argue that the rejection based upon binding to VT2 variants is moot due to deletion of this criticality in the claims.

The examiner has considered applicants' argument, and finds it persuasive concerning binding to VT2 variants.

Applicants argue that the specification does define the epitope by means of a competition assay and other antibodies binding to this epitope can thus be identified by competition with VTm1.1.

The examiner has considered applicants' argument, but does not find it persuasive. The identity of the specific epitope is totally dependent on the binding characteristic of applicants' antibody VTm1.1. Without the deposit of the antibody under the Budapest Treaty and its availability to other investigators, the specific identity of the epitope remains unknown and the identity of any antibody which may bind to this unknown epitope remains indeterminant.

New Rejections Necessitated by Amendment

Claim Rejections - 35 USC § 112

15. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

16. Newly amended claim 5 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for humanized mouse antibodies which neutralize VT2, does not reasonably provide enablement for humanized mouse antibodies which bind specifically to

Art Unit: 1645

VT2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention of newly amended claim 5 now is drawn to a humanized antibody which specifically binds to VT2

The state of the prior art as evidenced by applicants specification teach that there are two types of Verotoxin, i.e., VT1 and VT2. Thus, there is a lack in the art that any particular antibody binding to Verotoxin specifically binds to only VT2.

The amount of direction/guidance/working examples present in the instant specification is insufficient for the broad scope of the claim, i.e., any humanized antibody which binds specifically to only VT2. The specification teaches only one humanized mouse antibody which neutralizes VT2, but this antibody is not shown to comprise the necessary specificity characteristic of the claimed antibody.

Conclusion

17. No claims are allowed.

Art Unit: 1645

18. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

19. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Application/Control Number: 09/700,851

Page 7

Art Unit: 1645

system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



RODNEY P SWARTZ, PH.D
PRIMARY EXAMINER

Art Unit 1645

April 10, 2007